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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,459	08/25/2005	Wen-Cherng Lee	A158 US	2278

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Biogen Idec
14 Cambridge Center
Cambridge, MA 02142

EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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05/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,459	Applicant(s) LEE ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,9-19,34 and 36-49 is/are rejected.
- 7) ☒ Claim(s) 3-5,7,8,20-33 and 35 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/05, 5/16/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. According to a preliminary amendment filed on Oct. 4, 2004, the applicants have amended claim 44.
2. Claims 1-49 are pending in the application.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 36-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least

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four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, state of the prior art, unpredictability and the breadth of claims.

The specification mentions on page 2, lines 30-31 that the instant compounds are potent antagonists of the TGFB family type I receptors and mentions various assays on pages 73-76. However, there is no teaching in the specification regarding actual antagonist activity observed of any specific compounds encompassed by generic formula (I) in any one of these assays. There is no teaching either in the specification or prior art that structurally closely related compounds are well known in the art to have antagonist activity at TGFB type I receptors. There is no teaching in the specification or prior art regarding well established utility of TGFB type I receptor antagonists for treating every known fibrotic condition or tumor in the art. There are no working examples present showing efficacy of instant compounds in animal models of any fibrotic condition or any tumor cell line. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables Ra, m, R1, A1, A2, X, Y and R2 and therefore, in absence of such teachings, guidance and working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of every known fibrotic condition or tumor cell lines of every known tumor cell line and hence their utility for treating but not preventing these disease conditions.

In regard to preventing any disease condition, it is well known in the art that there are multiple mechanisms involved in the etiology of any known disease condition in the art.

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Therefore, correcting only one of these several mechanisms (such as inhibitory activity at TGFB type I receptors in the instant case) will not completely cure or prevent that specific disease condition.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 6 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Le Count (J. C. S. Chem. Comm. , cited on applicants form 1449).

Le Count discloses reaction of 5-chloropyridin-2-yl-thioureas with phenacyl bromides.

The compound (3) where R1 represents morpholine (see page 282) anticipates the instant claims when R1 represent a phenyl group and X represents heterocycloalkyl group in the instant compounds of formula (I).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 6, 9-19, 34, 36, 38, 40, 42, 44, 45, 47 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaster (WO 02/055077, cited on applicant's form 1449)

Gaster discloses imidazolyl-cyclic acetal derivatives as inhibitors of TGFB signaling pathway. The compounds disclosed in examples 1-5 (see pages 10-12) by gaster anticipate the instant claims when both a1 and A2 represent N, R1 represent heteroaryl group and X represents heterocycloalkyl group in the instant compounds of formula (I).

Allowable Subject Matter

8. Claims 3-5, 7, 8, 20-33 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625

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